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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,419	03/08/2000	Julie A. Meek	9110-0008	1596

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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/520,419

Applicant(s)

MEEK ET AL.

Examiner

Carolyn M Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 8 March 2000. Claims 1-20 are pending. An IDS statement has not been entered or considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 8-11, 14-16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (5,976,082).

(A) As per claim 1, Wong discloses a method of identifying patients at high risk of adverse health outcomes (col. 1 lines 9-12, col. 2 lines 31-45, col. 3 lines 42-48, col. 5 lines 13-25 and 31-40, and col. 15 lines 58-67) comprising:

(a) receiving (reads on "collecting"), storing, and extracting information from a patient record (reads on "individual") for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, and col. 17 line 49 to col. 18 line 4);

(b) assigning, based upon information from a patient record, a separate value to each predictor of the set of predetermined criteria or predictors (Abstract lines 1-24, col. 2 lines 61-62, col. 4 lines 62-66, col. 5 lines 3-12, col. 6 lines 44-51 and lines 64-67, col. 8 lines 18-22, col. 12 lines 27-39, and col. 13 lines 1-41); and

(c) generating, based upon a prediction model and the separate values assigned to the predetermined set of criteria or predictors, risk subgroups (reads on "risk level") of the patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (Fig. 6A-6B, Abstract lines 1-24, col. 1 lines 48-60, col. 2 lines 38-45 and lines 64-67, col. 3 lines 1-7, col. 3 lines 42-48, col. 4 line 65 to col. 5 line 3, col. 5 lines 13-25, col. 6 lines 44-63, col. 8 lines 33-35, col. 12 lines 7-18, col. 13 lines 51-60, and col. 18 lines 15-23 and lines 28-41).

(B) As per claim 5, Wong discloses:

(a) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(b) assigning, based upon information, a first dichotomous value, such as "1", to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined

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level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(c) assigning, based upon information, a second dichotomous value, such as "0", to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

(C) As per claim 8, Wong discloses defining, based upon risk subgroups (reads on "risk level"), whether a high risk exists of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-25, col. 5 lines 31-40, col. 6 lines 44-51, and col. 13 lines 51-60), and defining, based upon information from a patient, a targeted intervention for a patient in response to defining that a high risk exists of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-25, col. 5 lines 31-65, col. 6 lines 44-51, col. 13 lines 51-60, and col. 15 lines 58-67).

(D) As per claim 9, Wong discloses generating, based upon separate values assigned to each predictor and a model generated using multiple logistic regression, a risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 lines 49-58).

(E) As per claim 10, Wong discloses generating, based upon separate values assigned to the set of predictors and a model generated using multiple logistic regression, a probability or likelihood indicating the risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 line 60 to col. 15 line 67).

(F) System claim 11 differs from method claim 1 by reciting hardware elements, namely, a processor and memory comprising a plurality of instructions. As per these elements, Wong teaches:

- (a) a computer for processing information (col. 3 line 61 to col. 4 line 23); and
- (b) a storage medium storing software, wherein the computer for processing information executes operations stored on the storage medium (col. 3 line 61 to col. 4 line 23).

The remainder of system claim 11 repeats the same limitations of method claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(G) System claims 14 and 15 repeat the same limitations as claims 8-9 and 11, and are therefore rejected for the same reasons given above for those claims, and incorporated herein.

(H) Claims 16 and 19 repeat the subject matter of method claims 1 and 8, respectively, as a computer readable medium comprising a plurality of instructions executed by a healthcare management system to carry out the series of steps from method claims 1 and 8. As the underlying processes of claims 1 and 8 have been shown to be fully disclosed by the teachings of Wong in the rejections of claims 1 and 8, it is readily apparent the data processing system disclosed by Wong comprised of a computer for processing information (col. 1 lines 9-12 and col. 3 line 61 to col. 4 line 23) and a storage medium storing software, wherein the computer for processing information executes operations stored on the storage medium (col. 3 line 61 to col. 4 line 23), provides the means to carry out these steps. As such, these limitations are rejected for the same reasons given above for method claims 1 and 8, and incorporated herein.

Claim Rejections - 35 USC § 103

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1 and 16 above, and further in view of Mebane (5,486,999).

(A) As per claim 2, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong fails to expressly disclose presenting an individual with a self assessment questionnaire designed to elicit information from an individual for a predetermined set of predictive factors. However, Wong includes receiving (reads on "collecting"), storing, and extracting information from a patient data record or file (reads on "individual") for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4). Note, Wong receiving information in a patient file is considered to be a form of eliciting information from an individual.

Mebane discloses presenting a patient with a Lifestyle Questionnaire designed to determine selected lifestyle characteristics of the patient, wherein the questionnaire

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contains a set of input variables used to determine health care utilization (Fig. 4A, col. 2 lines 10-28, col. 5 lines 1-67, col. 6 Table 1, and col. 16 –18 Appendix A).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Mebane within the method taught by Wong with the motivation of improving the quality of treatment and outcomes for patients and reducing the cost for health care services by analyzing information about a patient's medical history and record (Wong; col. 2 lines 38-45).

(B) As per claim 3, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses a predetermined set of criteria or predictors, wherein the predictors include past healthcare use factors, such as number of hospitalizations, emergency services, or physician office visits, demographic factors, such as gender or age, and disease factors, such as diabetes or congestive heart failure (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-52, col. 5 lines 1-12, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-67, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

In addition, insofar as Applicant recites "predetermined set of predictive factors consisting of...", it is irrelevant whether or not Wong and Mebane disclose every single statement recited in the claim.

The remainder of claim 3 repeats the same limitations as claim 2, and is therefore rejected for the same reasons given for claim 2, and incorporated herein. The

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motivation for combining Mebane with Wong is given above in claim 2, and incorporated herein.

(C) Claim 17 repeats the subject matter of method claim 3, respectively, as a computer readable medium comprising a plurality of instructions executed by a healthcare management system to carry out the series of steps from method claim 3. As the underlying processes of claim 3 have been shown to be fully disclosed by the teachings of Wong and Mebane in the rejections of claim 3, it is readily apparent the data processing system disclosed by Wong and Mebane comprised of a computer for processing information (col. 1 lines 9-12 and col. 3 line 61 to col. 4 line 23) and a storage medium storing software, wherein the computer for processing information executes operations stored on the storage medium (col. 3 line 61 to col. 4 line 23), provides the means to carry out these steps. As such, these limitations are rejected for the same reasons given above for method claim 3, and incorporated herein.

6. Claim 4, 12-13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1, 11, and 16 above, and further in view of Silver (6,269,339).

(A) As per claim 4, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses receiving (reads on “collecting”), storing, and extracting information from a patient data record or file (reads on “individual”) for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

Wong fails to expressly disclose presenting, to a web browser, a questionnaire that elicits information from an individual for a predetermined set of predictive factors, and receiving the information via a web browser in response to presenting the questionnaire.

Silver discloses presenting on a client computer system, over the Internet an interface for data input (reads on “web browser”), wherein the interface includes a questionnaire for inputting information from a patient for a set of relative risk factors (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), and receiving the information at a server over the Internet in response to presenting the questionnaire through an interface for data input (reads on “web browser”) (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), wherein the client computer system and the server communicate using the NetBIOS protocol (col. 7-8).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Silver within the method taught by Wong with the motivation of improving the quality of treatment and

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outcomes for patients and reducing the cost for health care services by analyzing information about a patient's medical history and record (Wong; col. 2 lines 38-45), and providing a convenient means and decreasing the time to submit, update, and access information (Silver; col. 3 lines 49-51, col. 4 lines 48-64, and col. 8 lines 15-40).

(B) Claims 12 and 13 repeat the subject matter of method claim 4, respectively, as a set of apparatus elements rather than a series of steps. As the underlying processes of claim 4 have been shown to be fully disclosed by the collective teachings of Wong and Silver in the above rejections of claim 4, it is readily apparent that the system disclosed collectively by Wong and Silver includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claim 4, and incorporated herein.

(C) Claim 18 repeats the subject matter of method claim 4, respectively, as a computer readable medium comprising a plurality of instructions executed by a healthcare management system to carry out the series of steps from method claim 4. As the underlying processes of claim 4 have been shown to be fully disclosed by the teachings of Wong and Silver in the rejections of claim 4, it is readily apparent the data processing system disclosed by Wong and Silver comprised of a computer for processing information (col. 1 lines 9-12 and col. 3 line 61 to col. 4 line 23) and a storage medium storing software, wherein the computer for processing information executes operations stored on the storage medium (col. 3 line 61 to col. 4 line 23), provides the means to

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carry out these steps. As such, these limitations are rejected for the same reasons given above for method claim 4, and incorporated herein.

7. Claims 6-7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1 and 16.

(A) As per claims 6 and 7, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong fails to expressly disclose determining whether each predictive factor of a set of predictive factors is indicative of a high risk of an individual utilizing healthcare services at a predetermined level within a prospective time span, assigning a first dichotomous value or a "1" to each separate value of each predictive factor of the set of predictive factors that is determined to be indicative of a high risk, and assigning a second dichotomous value or a "0" to each separate value of each predictive factor of the set of predictive factors that is determined to not be indicative of a high risk.

However, Wong discloses the following for a single predictor:

(a) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

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(b) assigning, based upon information, a first dichotomous value, such as "1", to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(c) assigning, based upon information, a second dichotomous value, such as "0", to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

As per the recitation of additional or separate dichotomous values, the courts have broadly held that the duplication of parts is obvious. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). As such, these changes do not present a patentable distinction over the applied prior art of record.

(B) As per claim 20, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

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Claim 20 differs from claims 6 and 7 by reciting the step of generating, based upon a logistic regression formula of a predictive model and separate first dichotomous values and second dichotomous values assigned to the set of predictive factors, a risk level of the individual utilizing healthcare services at a predetermined level within a prospective time span. As per this element, Wong teaches:

(a) generating, based upon separate first dichotomous values and second dichotomous values assigned to each predictor and a model generated using multiple logistic regression, a risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 22-60, and col. 14 lines 49-58).

The remainder of claim 20 repeats the limitations of claims 6 and 7, and is therefore rejected for the same reasons given above for those claims, and incorporated herein.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a method of preparing a health potential analysis through a questionnaire (4,464,122), a method and apparatus for evaluating the insurability of a potentially insurable risk (4,975,840), a computer-based system for predicting future health of individuals (6,059,724), a method of managing the delivery of services by healthcare providers to medical patients

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including estimating charges of delivering healthcare services that take complicating factors into account (6,061,657), a method and apparatus for assessing a person's disease status (6,110,109), and a system for managing the health care of a plurality of members in a population including identification of member characteristics of one of the plurality of members (6,385,589).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The examiner can normally be reached on Monday-Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

10. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 305-7687 [Official communications; including After Final
communications labeled "Box AF"]

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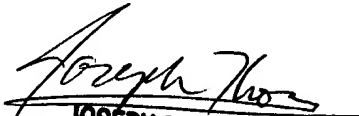
(703) 746-8374 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive,
Arlington, VA, 7th Floor (Receptionist).

CB

CB

August 12, 2002


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600